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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,491	03/02/2000	Vivian Berlin	APBI-P06-036	4943

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ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/517,491	Applicant(s) BERLIN, VIVIAN	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 7-7-2003 are acknowledged. Claims 51-55, 57, 59 and 61 have been amended. Claims 51-62 are pending and currently under examination.

Priority

The instant application is a continuation-in-part (CIP) of U.S. Application 08/250,795, filed on 5-27-1994. The instant claims are drawn to antibodies or fragments thereof that are immunoreactive with a mammalian RAPT1 protein comprising the sequence of SEQ ID NO:12. Said antibodies also do not substantially cross-react with a fungal TOR1 or TOR2 protein. Applicant asserts that the instant application is a continuation under 37 CFR 1.53(b) of U.S. Application 08/360,144, filed on December 20, 1994 and that a Request for Continuation indicating said priority claim accompanied the instant application when it was filed.

Contrary to Applicant's assertion, the only priority document listed in the filed declaration of the instant application is 08/250,795, filed on May 27, 1994 (see attached copy of said Declaration). Hence, Applications claim for any earlier priority date is unfounded. Consequently, since U.S. Application 08/250,795 does not disclose SEQ ID NO:12 or antibodies that are specifically immunoreactive to a RAPT1 protein and do not substantially cross react with a fungal TOR1 or TOR2 protein, the filing date of the instant application (3-2-2000) will be used with regard to the availability of prior art under 35 U.S.C. 102. It should be noted that the Request for Continuation referred to by Applicant in his response was not attached to said response as indicated by Applicant.

Claim Rejections Withdrawn

The rejection of claims 51 and 53-54 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "immunoreactive" is withdrawn in light of the amendment thereto.

The rejection of claims 51-55 57, 59 and 61 are rendered vague and indefinite by the use of the term "substantially cross-react" is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 51-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6-7, 9, 11, 13 and 16-17 of U.S. Patent No. 6,464,974 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to antibodies and antibody preparations that specifically immunoreact with proteins having greater

than 90 percent identity with SEQ ID NO:12 and do not cross-react with proteins with less than 90 percent identity with SEQ ID NO:12 (i.e. fungal TOR1 and TOR2 proteins). It should be noted that Applicant has indicated that a Terminal Disclaimer will be filed as needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 51-62 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berlin et al. (WO 95/33052) is maintained for reasons of record.

Applicant argues:

The cited reference is not available as prior art under 35 U.S.C. 102(b) since the priority date of the instant Application is December 20, 1994.

Applicant's arguments have been fully considered and deemed non-persuasive.

The priority date for the instant application, for the reasons set forth above, is March 2, 2000. Hence, the cited reference is not available as prior art under 35 U.S.C. 102(b).

As outlined previously, the instant invention is drawn to antibody preparations (both monoclonal and polyclonal) tha' specifically bind to a mammalian RAPT1 protein (or the fragment thereof represented by SEQ ID NO:12) and do not substantially cross react (binding affinity of less than 10 percent) with a fungal TOR1 or TOR2 protein.

Berlin et al. disclose the nucleic acid and amino acid sequence for mammalian RAPT1 (SEQ ID NO:11 and SEQ ID NO:12) which fully incorporates SEQ ID NO :12 of the instant application, as well as disclose the sequence of fragments of RAPT1 (see pages 67-104). Berlin et al. further disclose antibody preparations (both monoclonal and polyclonal) that are specifically immunoreactive with a mammalian RAPT1 protein and do not substantially cross react (binding affinity of less than 10 percent) with a fungal TOR1 or TOR2 protein (see page 39, line 10 to page 40, line 27). Berlin et al. do not specifically disclose that the aforementioned antibodies are specifically immunoreactive with a RAPT1 protein having an amino acid sequence that is at least 90 percent identical to SEQ ID NO:12 of the instant application.

However, since SEQ ID NO:12 codes for the biologically active region of the RAPT1 protein disclosed by Berlin et al., the antibodies raised against said RAPT1 protein would bind (i.e. immunoreact) with a protein with a 90 percent identity to SEQ ID NO:12. Hence, in the absence of evidence to the contrary, the antibody preparations of the instant application are merely obvious variants of the antibody preparations disclosed by Berlin et al. Berlin et al. do not explicitly disclose the disclose recombinant antibodies with the aforementioned properties. However, sequencing a known antibody so that it can be produced recombinantly constitutes a standard laboratory practice and hence would have been obvious to one of ordinary skill in the art.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
September 8, 2003

LYNETTE R. SMITH
SUPERVISOR